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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/815,715	04/02/2004	Henry Tao Peng	2515	9457
38392	7590	03/18/2008		
GEORGE A. SEABY SEABY & ASSOCIATES 250 CITY CENTRE AVENUE OTTAWA, ON K1R6K7 CANADA			EXAMINER LOVE, TREVOR M	
			ART UNIT 4131	PAPER NUMBER
			MAIL DATE 03/18/2008	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/815,715	Applicant(s) PENG ET AL.	
	Examiner TREVOR M. LOVE	Art Unit 4131	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-19 is/are pending in the application.
 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-19 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

ACTION STATUS SUMMARY

1. Claims 1-17 are pending.
2. The use of the trademark HYDROTHANE has been noted in this application. It should be capitalized wherever it appears and be accompanied by the generic terminology.
 - a. Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

Double Patenting

1. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

1. Claims 1-19 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-10 of copending Application No. 10/717528 (Turner) in view of U.S. Patent number 6,268,405 (Yao) and 4,396,377 (Roemer). This provisional rejection is proper because Turner discloses almost identical claims, wherein the Instant Claim set modifies the claims by considering aging, heating, and freezing the IPN of Turner. Roemer clearly discloses that aging is preferred to allow for the crosslinked polymer particles to have become substantially interpenetrated (Roemer, Column 11, lines 52-57). Roemer also states that the addition of heat to the curing stage is usually required (Roemer, column 12, lines 29-31). Therefore, the additions of aging and heat would have been obvious to one of ordinary skill in the art due to their positive effects on the crosslinking of the polymer. Yao clearly discloses the freeze-thaw method which strengthens the hydrogel (Yao, Column 2, lines 6-10, 16-18). It would be obvious to one of ordinary skill in the art to use said method to allow for reorganization of the polymeric components to create a stronger hydrogel. The numerical values that are stated in the Instant Claims are simply optimization of ranges, and therefore are not given patentable weight over the prior art set forth above.

This is a provisional obviousness-type double patenting rejection.

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 4, 7-10, 12-14, 16-18, are rejected under 35 U.S.C. 112 2nd paragraph as being indefinite.

a. **Instant Claims 4, 7-10, 12-14, 16-18** contains the trademark/trade name HYDROTHANE. Where a trademark or trade name is used in a claim as a limitation to identify or describe a particular material or product, the claim does not comply with the requirements of 35 U.S.C. 112, second paragraph. See *Ex parte Simpson*, 218 USPQ 1020 (Bd. App. 1982). The claim scope is uncertain since the trademark or trade name cannot be used properly to identify any particular material or product. A trademark or trade name is used to identify a source of goods, and not the goods themselves. Thus, a trademark or trade name does not identify or describe the goods associated with the trademark or trade name. In the present case, the trademark/trade name is used to identify/describe hydrophilic polyurethanes and, accordingly, the identification/description is indefinite.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

4. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

The applied reference (Turner) has two common inventors with the instant application (Martineau and Shek). Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art only under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 103(a) might be overcome by: (1) a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not an invention "by another"; (2) a showing of a date of invention for the claimed subject matter of the application which corresponds to subject matter disclosed but not claimed in the reference, prior to the effective U.S. filing date of

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the reference under 37 CFR 1.131; or (3) an oath or declaration under 37 CFR 1.130 stating that the application and reference are currently owned by the same party and that the inventor named in the application is the prior inventor under 35 U.S.C. 104, together with a terminal disclaimer in accordance with 37 CFR 1.321(c). This rejection might also be overcome by showing that the reference is disqualified under 35 U.S.C. 103(c) as prior art in a rejection under 35 U.S.C. 103(a). See MPEP § 706.02(l)(1) and § 706.02(l)(2).

Claims 1-5 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 6,331,578 (Turner) in light of U.S. Patent No. 4,396,377 (Roemer). Turner discloses a method of making an IPN, wherein the two components are hydrophobic and hydrophilic respectively (Turner, column 9, lines 12-13), wherein the hydrophobic component is preferred to be an elastomeric biocompatible polymer (Turner, column 11, lines 11-12), and wherein the hydrophilic component can be polyethylene oxide (Turner, column 11, lines 43-46), which is a biocompatible polymer. Also, the mixture forms a membrane (Turner, column 9, lines 11-14). Turner does not disclose the use of aging, however, Roemer does disclose the use of aging on an IPN to insure that the crosslinked polymer has become substantially interpenetrated (Roemer, column 12, lines 53-57). It would be obvious to one of ordinary skill in the art to allow the IPN of Turner to age to increase the amount of crosslinking that occurred. Turner further discloses that the hydrophobic component is a siloxane, as in instant claim 4 (Turner, column 11, line 13-15), and the reaction mixture of the above components also has a crosslinker as required in claim 2 (Turner, column 22, lines 55-58). Turner further

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discloses that the membrane, which is an elastomeric polymer network, has the ability to expand and retract based on the environment (Turner, column 10, lines 56-60), and is thus a three-dimensional open mesh as specified in claim 3. Also, Turner further discloses that the hydrophilic component is polyethylene oxide (Turner, column 11, lines 43-46).

Turner does not disclose aging, or the addition of heat as in claim 5, however Roemer in referring to aging, further discloses that the application of heat is usually required for curing (Roemer, column 12, lines 29-31). It would be obvious to use the aging and heating of Roemer to create a more interpenetrated polymer network.

Claim 6 is rejected under 35 U.S.C. 103(a) as being unpatentable over the Turner and Roemer for the reason set forth above, and further in view of U.S. patent 6,268,405 to Yao. Turner does not disclose freeze-drying, however, Yao) discloses the freeze-thaw crosslinking method. It would be obvious to one of ordinary skill to use the freeze-thaw method to increase the mechanical strength of the IPN(Yao, column 2, lines 6-7, and 16-18).

Claims 7-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Turner and Roemer for the reasons set forth above in further view of U.S. Patent No. 4,966,953 (Shikinami). Turner teaches the disclosure as set forth above but fails to teach polyurethane or gelatin as in claim 7. Shikinami, while teaching a polyurethane gel, discloses that both polyurethane and gelatin are polymer compounds which can form hydrogels (U.S. Patent 4,966,953, Shikinami, column 1, line 48 – column 2, line 2). It

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would be obvious to one of ordinary skill in the art to modify Turner by using polyurethane and gelatin since they can both be crosslinked relatively easily.

Turner further discloses that the hydrophilic component's constituents may be any crosslinkable water soluble polymer, prepolymer, or copolymer. Turner continues on to disclose that methacrylates are one of the preferred options (Turner, column 11, lines 43-48). Though Turner does not directly teach gelatin, it can be seen from the discussion of Instant Claim 7, namely Shikinami, that it would be obvious to one of ordinary skill in the art to use gelatin as said hydrophilic component, but Turner further shows that a methacrylate, which can include of gelatin, would be even better.

Therefore, it would be obvious to one of ordinary skill in the art to create said methacrylate by adding methacrylic anhydride to the gelatin which would inevitably create even greater crosslinking within the gelatin as claimed in claim 8. Also, to initiate the crosslinking, it is well known in the art to use UV radiation (Turner, column 1, lines 44-46; column 14, lines 33-36).

Roemer discloses the use of aging to increase crosslinking as in instant claims 9-10.

The length of the aging is simply an optimization of ranges. It would be obvious to the artisan to test the ranges to determine which achieved the greatest crosslinking.

The amount of time and the temperature, as in instant claims 11-12 are simply an optimization of ranges. It would be obvious to the artisan to test the ranges to determine which achieved the greatest crosslinking.

Turner does not discuss freeze-drying as in claims 13-14. Yao does disclose the freeze-thaw method for the use of increasing the mechanical strength of a hydrogel

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(Yao, column 2, lines 5-18). The freeze-thaw method is a method wherein the components are frozen and then thawed. This is the same as the freeze drying set forth in Instant Claims 13 and 14 because for the freeze drying to be effective on a hydrogel, it would have to be rehydrated/thawed. Also, the temperature at which the freezing occurred is simply an optimization of ranges, and it would be obvious to the artisan to test the ranges to determine which achieved the greatest crosslinking.

Turner discloses a method of making an IPN, wherein the two components are hydrophobic and hydrophilic respectively (Turner, column 9, lines 12-13), wherein the hydrophobic component is preferred to be an elastomeric biocompatible polymer (Turner, column 11, lines 11-12), and wherein the hydrophilic component can be polyethylene oxide (Turner, column 11, lines 43-46), which is a biocompatible polymer. Also, the mixture forms a membrane (Turner, column 9, lines 11-14). Turner does not disclose the use of a freeze-drying method as in claim 15. However, Yao does disclose such a method as the freeze-thaw method, the motivation being that it would increase the mechanical strength of the IPN (Yao, column 2, lines 5-18).

Turner goes on to teach the disclosure as set forth above but fails to teach polyurethane or gelatin as in claim 16. Shikunami, while teaching a polyurethane gel, discloses that both polyurethane and gelatin are polymer compounds which can form hydrogels (U.S. Patent 4,966,953, Shikunami, column 1, line 48 – column 2, line 2). It would be obvious to one of ordinary skill in the art to modify Turner by using polyurethane and gelatin since they can both be crosslinked relatively easily. Turner further discloses that the hydrophilic component's constituents may be any crosslinkable water soluble polymer,

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prepolymer, or copolymer. Turner continues on to disclose that methacrylates are one of the preferred options (Turner, column 11, lines 43-48). Though Turner does not directly teach gelatin, it can be seen from the discussion of Instant Claim 7, namely Shikinami, that it would be obvious to one of ordinary skill in the art to use gelatin as said hydrophilic component, but Turner further shows that a methacrylate, which can include of gelatin, would be even better. Therefore, it would be obvious to one of ordinary skill in the art to create said methacrylate by adding methacrylic anhydride to the gelatin which would inevitably create even greater crosslinking within the gelatin. Also, to initiate the crosslinking, it is well known in the art to use UV radiation (Turner, column 1, lines 44-46; column 14, lines 33-36).

The temperature of the freezing process specified in claim 17 is simply an optimization of ranges, and it would be obvious to the artisan to test the ranges to determine which achieved the greatest crosslinking.

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Turner does not teach the use of aging, as in claim 18, however, it is disclosed in Roemer to use aging for an IPN to insure that the crosslinked polymer has become substantially interpenetrated (Roemer, column 12, lines 53-57). It would be obvious to one of ordinary skill in the art to allow the IPN of Turner to age to increase the amount of crosslinking that occurred. The length of the aging is simply an optimization of ranges, and it would be obvious to the artisan to test the ranges to determine which achieved the greatest crosslinking.

The criticality of the concentrations of the methacrylated gelatin in claim 19 have not been shown, as such, the concentrations are determined to be mere optimization of

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ranges, and it would be obvious to the artisan to test the ranges to determine which achieved the greatest crosslinking.

NO CLAIM IS ALLOWED.

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure: U.S. Application 09/645394.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to TREVOR M. LOVE whose telephone number is (571)270-5259. The examiner can normally be reached on Monday-Friday 7:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Janet Andres or Cecilia Tsang can be reached on 571-272-0867 or 571-272-0562, respectively. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/JANET L. ANDRES/

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Supervisory Patent Examiner, Art Unit 4131

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